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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,883	04/13/2007	Gregory James Roger	FBRIC59.001APC	1548

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KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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STEWART, JASON-DENNIS NEILKEN

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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09/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/586,883	<b>Applicant(s)</b> ROGER, GREGORY JAMES	
	<b>Examiner</b> JASON-DENNIS STEWART	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23, 24 and 28 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-22 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

The following is a Final Office action in response to communications received on 06/11/2008. Claims 1, 2, 5, and 23 have been amended. Therefore, Claims 1-28 are pending and addressed below.

### ***Response to Amendment***

The amendments are sufficient to overcome the U.S.C. 112, 2<sup>nd</sup> paragraph rejection of the previous Office action.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 8, 9, 11, 13-15, 18, 21, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Otte 6,468,305. The annular body is mountable to the inner surface of the support ring and cusps rotatable within the annular body (Fig. 5). The outer surface of the support ring is engageable to a vessel wall (Fig. 4).

Art Unit: 3738

3. Regarding Claims 1 and 2, Otte discloses moveable leaflets 152, annular body 12 and support ring 14. The annular body is moveable and rotatable relative to the support ring from a sealed to an unsealed position (col. 2, ll. 35-50).
4. Regarding Claim 3, the leaflets are capable of moving to a closed position due to a second pressure differential.
5. Regarding Claim 4, it is inherent that a higher pressure upstream would cause the leaflets of the valve to open as it would in a natural heart valve.
6. Regarding Claim 5, it is inherent that higher pressure downstream would cause the leaflets to close as in a natural valve.
7. Regarding Claim 8, Otte illustrates leaflets extending inwardly from and at an angle to the annular body portion when in their closed position (Fig. 5).
8. Regarding Claim 9, Otte illustrates leaflets forming a convex body that extends away from the annular body portion (Fig. 5).
9. Regarding Claim 11, Otte illustrates leaflets that are fully capable of progressive movement upon progressive change of pressure (Figs. 5 and 6).
10. Regarding Claims 13 and 14, Otte illustrates leaflets 18 that are hingedly connected to the annular body portion (Fig. 3A).
11. Regarding Claim 15, Otte illustrates a valve made from bioprosthetic tissue (Fig. 6).
12. Regarding Claim 18, Otte discloses the annular body made from pyrolytic carbon (col. 3, ll. 11-25).

Art Unit: 3738

13. Regarding Claims 21, 25 and 26, Otte discloses a method of delivering the implant into a vessel where the support ring is delivered separately (col. 3, ll. 12-25).

14. Regarding Claim 22, Otte discloses mitral and aortic valve (col. 2, ll. 19-21).

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otte 6,468,305 further in view of Quijano et al. 5,500,014.

Otte discloses the invention as claimed and as discussed above. However, Gorshkov in view of Sutherland in view of Otte does not disclose overlapping leaflets.

Quijano discloses overlapping leaflets (col. 9, ll. 20-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the overlapping leaflets of Quijano in order to ensure that the valve stays open under normal blood flow conditions but closes under minimal backflow pressure as taught by Quijano (abstract).

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otte 6,468,305 in view of Child 3,835,475.

Otte discloses the invention as claimed and as discussed above. However, Gorshkov in view of Sutherland in view of Otte does not disclose a coating to reduce turbulence of fluid flowing past and/or over the leaflets.

Art Unit: 3738

Child discloses a silicon-alloyed Pyrolite carbon coating (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the coating of Child in order to increase thromboresistance as taught by Child (col. 2, ll. 20-25).

4.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Gorshkov in view of Sutherland with the bioprosthetic tissue of Otte in order to implant a valve in the mitral or aortic valve orifice as taught (col. 2, ll. 16-21).

5. Claims 16, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otte 6,468,305 in view of Gorshkov et al. 5,197,980.

6. Regarding Claim 16, Otte discloses the invention as claimed and as discussed above. Although implied, Otte does not disclose leaflets made from an artificial material.

Gorshkov teaches leaflets made from pyrolytic carbon (col. 5, ll. 12-15). Regarding Claim 17, Gorshkov also teaches a support ring made of metal alloy such as cobalt (col. 5, lines 16-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the material disclosed in Gorshkov in order to form valvular cusps that are biocompatible as taught by Groshkov (abstract). Additionally, it would have been obvious to one of ordinary skill to substitute support ring

Art Unit: 3738

materials and use cobalt as taught by Gorshkov in Otte's valve device since such a modification only involves routine skill in the art.

7. Regarding Claim 20, Otte discloses the invention as claimed and as discussed above. However, Otte does not disclose providing the annular body and support ring as a single unit.

Gorshkov illustrates a valve mechanism that is capable of being delivered as a single unit (Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the material disclosed in Gorshkov in order to form valvular cusps that are biocompatible as taught by Groshkov (abstract).

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otte 6,468,305 further in view of Cohen 4,599,081.

Otte discloses the invention as claimed and as discussed above. However, Gorshkov in view of Sutherland in view of Otte does not disclose a turbine member.

Cohen discloses a turbine member that translates and rotates to cause occlusion or unocclusion of a valve (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Otte with the turbine of Cohen in order to provide an artificial heart valve with a high speed occluder and substantially no noise as taught by Cohen (col. 5, ll. 7-10).

***Allowable Subject Matter***

9. Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 23, 24, and 28 are allowed. The prior art does not teach or suggestion alone or in combination an annular body that moves from a sealed to an unsealed position defining a second pathway *when the assembly is subject to the first pressure differential*.

***Response to Arguments***

11. Applicant's arguments filed -6/11/2008 have been fully considered but they are not persuasive. Applicant argues that Otte does not disclose or suggest a second fluid pathway defined by the annular body and the support ring. Examiner respectfully disagrees. Otte discloses an annular body and a support ring that can be unsealed and separated with one another. When these two portions are unsealed from one another, it is inherent that a second fluid pathway would be established that is defined by the annular body and the support ring. Furthermore, it should be noted that a small degree of backflow through portion of a prior art valves is well known and discussed (see Gorshkov et al. 5,197,980 for example, col. 8, ll. 5-10, for example). The limitation "for the flow of fluid in the first direction" is seen as a functional limitation by the Examiner and does not distinguish the Applicant's invention structurally over the prior art.



***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
/Jason-Dennis Stewart/  
Examiner, Art Unit 3738

/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738